IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

Charles Ouellette; Amelia Arnold; Maine Pharmacy Association; Maine Society of Health-System Pharmacists; Retail Association of Maine; Pharmaceutical Research and Manufacturers of America ("PhRMA"), **Plaintiffs** **v.** **Janet Mills, in her official capacity as Attorney General of the State of Maine; H. Sawin Millett, Jr., in his official capacity as Commissioner of Administrative & Financial Services for the State of Maine,** **Defendants**	**No. _____** **COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF** **INJUNCTIVE RELIEF REQUESTED**

INTRODUCTION

1. The State of Maine has enacted a law ("the Importation Law") that expressly authorizes foreign pharmaceutical vendors to export prescriptions drugs into the United States, circumventing the carefully-constructed closed federal regulatory structure governing prescription drugs and thus posing serious health risks to consumers. This attempt to circumvent federal law is no accident: Maine's Importation Law was enacted with the avowed purpose of opening the state's borders to foreign pharmacies, after previous iterations of drug importation programs operating in the state ended in the wake of the state Attorney General's declaration of their illegality.

2. Prescription drugs shipped into Maine by foreign pharmacies pursuant to the Importation Law are not subject to any of the quality and safety controls put in place by the federal government in order to protect persons who rely on prescription medications. The Importation Law therefore puts Maine residents at risk of serious harm.

3. The Importation Law conflicts with the considered judgment of the federal government concerning the importation of foreign drugs, poses an obstacle to the federal government's ability to achieve the goals of its prescription drug regulatory regime, and is an invalid attempt at legislating in a field totally occupied by the federal government. Moreover, the Importation Law is an encroachment by the state of Maine of the federal government's exclusive power to regulate foreign commerce.

4. This Court should therefore grant a preliminary injunction and issue a declaration and a final judgment barring Maine from implementing its pharmaceutical importation law.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1983, and 2201. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (e).

PARTIES

6. Plaintiff Charles Ouellette is a pharmacist licensed under the laws of the State of Maine. He is the owner and operator of Saint John Valley Pharmacy in Fort Kent, Maine, a pharmacy licensed under the laws of the State of Maine.

7. Plaintiff Amelia Arnold is a pharmacist licensed under the laws of the State of Maine. She is a clinical pharmacist at Community Pharmacies in Augusta, Maine, which are licensed pharmacies under the laws of the State of Maine.

8. Plaintiff Maine Pharmacy Association ("MPA") is a non-profit organization that has been serving the interests of pharmacy in Maine since 1867. It currently has 390 total members including pharmacists, pharmacy technicians, and pharmacy interns who are licensed in Maine. In bringing this lawsuit, MPA seeks to vindicate the interests of its members, who are being injured by the Importation Law, and to advance its stated goal of seeking the enactment of sound pharmacy-related laws in Maine in order to protect and promote the public health and

welfare as well as to advance the interests of pharmacy practitioners. The individual members of MPA are not indispensible to the proper resolution of the case.

9. Plaintiff Maine Society of Health-System Pharmacists ("MSHP") is a non-profit professional organization whose membership includes pharmacists, pharmacy technicians and other related professionals who practice in health-system and community pharmacy settings. It is an affiliated state chapter of the American Society of Health-System Pharmacists. MSHP seeks to support Maine pharmacies and pharmacists in their mission of providing efficient, safe, and cost-effective pharmaceutical services to Maine residents. The individual members of MSHP are not indispensible to the proper resolution of the case.

10. Plaintiff Retail Association of Maine ("RAM") is a non-profit organization that conducts lobbying and issue-education efforts on behalf of Maine retailers. RAM's Community Pharmacy Group counts among its member retailers both chain and independent pharmacies, whose interests RAM represents before the state's elected officials. The individual members of RAM are not indispensible to proper resolution of the case.

11. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") is a non-profit organization representing pharmaceutical research and biotechnology companies that produce brand-name prescription drugs. In bringing this lawsuit, PhRMA seeks to vindicate the interests of its members, who are being injured by the Importation Law, as well as its own interests. The individual members themselves are not indispensible to the proper resolution of the case.

12. Defendant Janet Mills is the Attorney General of the State of Maine. She is sued in her official capacity. The State Attorney General has the responsibility of enforcing and defending the State's laws, as evidenced by the previous Attorney General's actions to halt the

importation of foreign drugs into Maine, in violation of state licensing laws.

13. Defendant H. Sawin Millett, Jr., is the Commissioner of Administrative & Financial Services for the State of Maine. He is sued in his official capacity. The Division of Employee Health & Benefits, which is a division of the Maine Bureau of Human Resources within the Maine Department of Administrative and Financial Services, oversees the provision of health insurance benefits to state employees and their families and will be responsible for implementing any state-run program to import pharmaceuticals from foreign countries.

FACTS

A. Federal Law Restricts The Importation Of Prescription Drugs

14. In the Federal Food, Drug, and Cosmetic Act ("the FDCA"), Congress created a comprehensive regulatory scheme that strictly limits the importation or introduction into interstate commerce of prescription drugs.

15. The FDCA prohibits the importation or introduction into interstate commerce of any "new drug" that has not received approval from the Food and Drug Administration ("the FDA") under an exacting statutory scheme that regulates the manufacturing processes, labeling, and packaging of pharmaceutical products. 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.50.

16. The FDCA prohibits importation or introduction into interstate commerce of any prescription medicines that have not been labeled in accordance with federal law, including requirements pertaining to the content of warning labels and use of the English language. *See* 21 U.S.C. §§ 352, 353; 21 C.F.R. § 201.15(c).

17. The FDCA prohibits importation or introduction into interstate commerce of any prescription medicine dispensed without a valid prescription issued by a licensed practitioner. *See* 21 U.S.C. § 353(b); *see also id.* §§ 331(a)-(d).

18. In 1988, Congress enacted a special restriction on importation of "American

goods returned." *See* Prescription Drug Marketing Act, P.L. 100–293 (Apr. 22, 1988), codified at 21 U.S.C. § 381(d)(1). That restriction prohibits any person other than the original manufacturer to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad. *See* 21 U.S.C. § 381(d)(1). Congress specifically found that this restriction was necessary to protect the health and safety of the American public because "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Prescription Drug Marketing Act, P.L. 100-293 § 2

19. Congress also enacted the Medicaid Prescription Drug, Improvement, and Modernization Act ("MMA") in 2003, which, in pertinent part, authorizes the Secretary of Health and Human Services to "promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." 21 U.S.C. § 384(b). The MMA authorizes the Secretary to "grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition on importation of a prescription drug." *Id.* § 384(j)(2)(A). However, these provisions become effective only when the Secretary certifies to Congress that importation will be safe and cost-effective. *See id.* § 384(l). To date, no such certifications or regulations have been issued. *See* 21 C.F.R. §§ 200–369.

B. The FDA Has Consistently Warned States Not To Authorize Importation Of Foreign Drugs, And The Secretary Of Health And Human Services Has Refused To Certify That Importation Of Prescription Drugs Would Be Safe Or Cost-Effective

20. As the FDA has repeatedly stated, "virtually all prescription drugs imported for personal use into the United States from Canada" or other countries "violate the FDCA because they are either unapproved new drugs[,] labeled incorrectly[,] or dispensed without a valid

prescription." Letter from Randall D. Lutter to Gov. Kenny Guinn (May 20, 2005), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm179414.htm (last visited Sept. 10, 2013) ("Guinn Letter"). Indeed, foreign prescription drugs are not subjected to the manufacturer-specific and product-specific FDA approval process, or labeled with all of the information required by federal law. *See id.*; *see* 21 U.S.C. §§ 352-355; 21 C.F.R. § 314.50; *see also* 21 U.S.C. § 381(d)(1) (prescription drugs manufactured in the United States and sent to other countries may lawfully be imported back into the United States only by the original manufacturer); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 789 (8th Cir. 2006) (finding that "Canadian prescription drugs at issue are not labeled in conformity with federal law" and "are not approved pursuant to" § 355).

21. The FDA has consistently and repeatedly informed states that importation of foreign pharmaceuticals—including from Canada—poses safety risks. *See generally* Importing Prescription Drugs, Letters To State And Local Officials, *available at* http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm (last visited Sept. 10, 2013) (collecting the agency's "official communication[s]" to officials in Hawaii, Minnesota, Washington, Maryland, Oregon, Texas, Nevada, Rhode Island, District of Columbia, Massachusetts, Wisconsin, New Hampshire, North Carolina, Illinois, and California).

22. In a letter to the Governor of Hawaii, for example, an FDA official explained that the agency "cannot provide adequate assurance that the drug products delivered to consumers in the United States from any foreign country, including Canada, U.K., Australia, or others are the same as products that the FDA has approved through its rigorous safety and efficacy review process." Letter from Randall D. Lutter to Gov. Linda Lingle (Aug. 14, 2008), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm179204.htm (last visited Sept. 10, 2013). "In fact," the FDA official continued, "many drugs that U.S. consumers purchase from Canada and believe

were made in Canada actually are shipped from other countries, such as India and Costa Rica, and originate from dozens of countries around the world." *Id.*

23. The FDA has supplied specific examples of the safety risks created when consumers attempt to import international pharmaceuticals in contravention of federal law. "For example," the agency wrote in a letter to the Governor of Nevada, "an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in Canada and to ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by the FDA for any use in the United Sates." Guinn Letter.

24. The FDA has also flagged the risks inherent in importing drugs originally manufactured in the United States. "In another instance," the agency explained, "a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes." *Id.* But, while "the drug originally had been manufactured in the United States, it was shipped back into the country in a manner that did not satisfy the refrigeration storage conditions specified in FDA-approved labeling and, therefore, could have potentially compromised the safety and effectiveness of the insulin." *Id.* "Because the failure to refrigerate the product may not change its appearance," the agency concluded, "American consumers may have had no way of knowing if their insulin had been mishandled abroad." *Id.*

25. In some instances, counterfeit medicines have entered the United States through unauthorized importation, placing patient safety at risk. One widely reported instance involved Avastin, a cancer medicine that—when lawfully produced by an authorized manufacturer—bears distinctive labeling. In recent years, however, Canadian, British, Turkish, and other foreign

pharmaceutical suppliers have arranged the unauthorized importation of what purported to be cut-rate Avastin into the United States. These products turned out to be counterfeit. *See* FDA Webpage, "Counterfeit Version of Avastin in U.S. Distribution" (Feb. 14, 2012), *available at* http://www.fda.gov/drugs/drugsafety/ucm291960.htm (last visited Sept. 10, 2013). As the FDA explained, "The counterfeit version of Avastin does not contain the medicine's active ingredient, bevacizumab, which may have resulted in patients not receiving needed therapy." *Id.*; *see also, e.g.*, Christopher Weaver et al., "Drug Distributor Is Tied To Imports of Fake Avastin," Wall Street Journal (Mar. 7, 2012), *available at* http://online.wsj.com/article/SB10001424052970203370604577261343974214110.html (last visited Sept. 10, 2013) ("Federal officials are examining the business dealings of two Canadian businessmen who have long histories in the Internet pharmacy trade that delivers discounted prescription drugs from overseas to U.S. citizens.").

26. The FDA has repeatedly emphasized the need to adhere to its strict labeling requirements in order to protect consumers from fraudulent products shipped from overseas. *See* FDA Webpage, "Counterfeit Version of Avastin in U.S. Distribution" ("FDA-approved version of Avastin vials and packaging have a 6-digit numeric batch number and expiration dates in a 3-letter month and 4-digit year format."). The FDA has had to issue additional warnings within the last year, including with regard to even more unauthorized importation of fake Avastin. *See* FDA Webpage, "Letters to Doctors about Risks of Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers" (Dec. 19, 2012), *available at* http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm#Doctors (last visited Sept. 10, 2013); *see also* "FDA Warns About Fake Avastin Again," CBS News (Feb. 7, 2013), *available at* http://www.cbsnews.com/8301-204_162-57568268/fda-warns-

about-fake-avastin-again (last visited Sept. 10, 2013).

27. The FDA has expressed particular concerns about CanaRx, a Canadian mail-order pharmacy, regarding its illegal importation of pharmaceuticals. For example, the FDA has concluded CanaRx's illegal shipments of prescription drugs into the U.S. "expos[es] U.S. consumers to risky imported drug products" and that "[t]his potential risk is compounded by the fact that CanaRx makes misleading assurances to consumers about the safety of its drugs." Statement of John M. Taylor, III before the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs (July 22, 2004), *available at* http://www.fda.gov/newsevents/testimony/ucm113635.htm (last visited Sept. 10, 2013). The agency also avers that it "has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigeration, in a manner that did not satisfy the storage conditions specified in FDA approved labeling, and which could potentially compromise the safety and effectiveness of the insulin." *Id.*

28. In some instances, states have attempted to support illegal pharmaceutical importation, with unfortunate results. Most saliently, then-Governor of Illinois Rod Blagoyevich helped create and promote the so-called "I-SaveRx Program," which contracted with CanaRx to facilitate medical importation from Canada and other countries. *See* Illinois Office of Auditor General, Report Digest, Management of the Flu Vaccine Procurement and the I-SaveRx Program at xvii (September 2006), *available at* http://www.auditor.illinois.gov/Audit-Reports/Performance-Special-Multi/Performance-Audits/FY06-Flu-Vaccine-ISaveRX-MGMT-digest.pdf (last visited Sept. 10, 2013). Unlike Maine's Importation Law, the Illinois program imposed at least some nominal safeguards to secure patient safety, such as purporting to limit the range of specific foreign pharmacies that could participate. But that program nonetheless

became the subject of a scathing critique from the Illinois Office of Auditor General. According to the Auditor General's report, the I-SaveRX Program was "in violation of federal law" regarding pharmaceutical importation. *See id.* at i; *id.* at xii ("The State's operation of the I-SaveRx Program, which imports prescription drugs into the United States, is in violation of federal law."); *id.* at xvi (same). Moreover, the Auditor General concluded that, despite the state's efforts to limit the quality of pharmaceutical importation, the imported medicines were actually subject to no effective monitoring whatsoever by state health authorities. As the Auditor General put it: "The State does not monitor whether prescriptions are being filled only by approved pharmacies," and "[p]articipants not knowing if their prescription was filled at an approved pharmacy questions the safety aspect of the I-SaveRX Program." *Id.* at xii; *id.* at xix. The Illinois program fell into disuse, particularly after its main supporter, then-Governor Blagoyevich, was impeached and removed from office.

29. Recognizing the safety risks posed by foreign drugs, the Secretary of Health and Human Services has declined to certify, under the MMA or otherwise, that importation of prescription drugs from Canada, or any other country, would be safe and cost-effective. *See, e.g.*, 21 U.S.C. § 384(b).

C. Prior To Enactment Of The Importation Law, Federal And Maine Law Created A Closed System For Licensed Maine Pharmacists To Dispense Prescription Drugs To Maine Patients

30. Prior to enactment of the Maine Importation Law, Maine law authorized only professionals licensed under the Maine Pharmacy Act and physicians, dentists, veterinarians, or other practitioners of the healing arts licensed under the laws of the State of Maine to dispense and administer prescription drugs to patients within Maine.

31. The Maine Pharmacy Act imposes significant burdens on individuals seeking to become licensed under the Act, including educational, examination, training, and fee-payment

requirements. *See* 32 M.R.S. § 13732. The Maine Pharmacy Act also imposes continuing pharmacy education and renewal-fee requirements on professionals seeking to renew their licenses under the Act. *See id.* §§ 13734–35. The Maine Pharmacy Act subjects licensed pharmacy professionals to the oversight and discipline of the Maine Board of Pharmacy. *See id.* §§ 13711–24.

32. The Maine Pharmacy Act imposes licensing and inspection requirements on pharmacies in Maine. *See id.* § 13751. Pharmacies in Maine are subject to the oversight of the Maine Board of Pharmacy. *See id.*

33. Professionals licensed under the Maine Pharmacy Act are subject to a broad array of rules, requirements, restrictions, duties, and obligations under federal and state law. Prior to enactment of the Maine Importation Law, these federal and state rules and requirements formed a closed system for distributing prescription drugs in Maine with the paramount concern of protecting patient health, safety, and welfare.

34. In the Omnibus Reconciliation Act of 1990 ("OBRA"), Congress imposed a number of legal duties on pharmacists dispensing prescription drugs to patients covered by Medicaid. Maine has enacted state laws that extend these duties to all professionals licensed under the Maine Pharmacy Act who dispense prescription drugs to any patient in Maine. The Maine Board of Pharmacy also has issued rules and regulations that bear on the duties and obligations of pharmacy professionals licensed under the Maine Pharmacy Act.

35. For example, Maine law requires the pharmacist to record every prescription and to verify the identity of the practitioner issuing it. *See* Maine Bd. of Pharmacy Rules Ch. 19.2, *available at* http://www.maine.gov/sos/cec/rules/02/chaps02.htm#392 (last visited Sept. 10, 2013).

36. Federal and state law also require licensed Maine pharmacists to perform a drug utilization review ("DUR") "before each prescription is filled or delivered to an individual[,] typically at the point-of-sale or point of distribution." 42 U.S.C. § 1396r-8(g)(2)(A)(i); *see also* Maine Bd. of Pharmacy Rules Ch. 25.1.1.

37. A DUR must "include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions[,] . . . incorrect drug dosage or duration of treatment, drug-allergy interactions, and clinical abuse/misuse." 42 U.S.C. § 1396r-8(g)(2)(A)(i); *see also* Maine Bd. of Pharmacy Rules Ch. 25.1.1.

38. To protect the safety of patients and guarantee the effectiveness of DURs, licensed Maine pharmacists also must make a "reasonable effort . . . to obtain, record, and maintain" each patient's "known allergies and drug reactions, and a comprehensive list of medications and relevant devices." 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(II); *see also* 32 MSRA § 13785.

39. Moreover, "[u]pon receipt of a prescription," a licensed Maine pharmacist "shall examine the patient's . . . record before dispensing the medication to determine the possibility of harmful drug interaction or reaction." 32 MSRA § 13785. "Upon recognizing a potentially harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which may include consultation with the practitioner." *Id.*

40. Licensed Maine pharmacists also must counsel patients regarding their prescription drugs, and must inform them of any special directions and precautions for preparation; the administration and use of the drug; any common and/or severe side or adverse effects; any possible interactions with other drugs; any therapeutic contraindications that the patient may encounter along with appropriate actions if they occur; any techniques for self-

monitoring, proper storage and refill information; and any actions to be taken in the event of a missed dose. 42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I); *see also* 32 M.R.S. § 13784; Maine Bd. of Pharmacy Rules Ch. 25.1.2.

41. Licensed Maine pharmacists also are subject to a comprehensive framework of regulations promulgated under the federal Health Insurance Portability and Privacy Act ("HIPAA") that safeguards patient privacy, confidentiality, and health information. *See, e.g.*, 45 C.F.R. Parts 160 and 164.

D. The MaineMeds, PortlandMeds, and HardwoodsMeds Programs Were Terminated Because They Allowed Importation Of Prescription Drugs By Unlicensed Foreign Pharmacies

42. In 2012, the State of Maine adopted the "MaineMeds" program, which allowed insured state employees to purchase prescription medications from foreign pharmacies through CanaRx, the Canadian mail-order pharmacy whose illegal importation of pharmaceuticals has been publicly condemned by the FDA. *See supra* ¶ 27. CanaRx acts as a broker dispensing drugs provided by pharmacies located in several countries throughout the world.

43. Because these foreign pharmacies were not licensed under state law, the Maine Board of Pharmacy contacted the Maine Attorney General's office for an opinion regarding the legality of the MaineMeds program. In 2012, Assistant Attorney General Carrie Carney advised the Board that CanaRx's participation in the program constituted unlicensed practice, and that state law prohibited the Board from licensing any foreign pharmacy. Then-Attorney General William J. Schneider reiterated this position to CanaRx. *See* Letter from William J. Schneider to Joseph A. Morris (June 21, 2012), *available at* http://media.kjonline.com/documents/CanaRx+AG+Letter+06+21+12.pdf (last visited Sept. 10, 2013).

44. CanaRx thereafter terminated the MaineMeds program, as well as the similar "PortlandMeds" program operated by the City of Portland, and the "HardwoodsMeds" program

operated by Hardwood Products Company, a Maine employer.

E. The Importation Law Permits Foreign Mail-Order Pharmacies To Dispense Prescription Drugs To Maine Patients Without Complying With The Requirements Of The Maine Pharmacy Law

45. In the wake of the termination of the MaineMeds, PortlandMeds, and HarwoodMeds programs, former participants in those programs lobbied the Maine Legislature to amend state law to permit those programs to resume operation.

46. The Maine Legislature enacted the Importation Law in June 2013 as 2013 Public Law Chapter 373, titled "An Act to Facilitate the Personal Importation of Prescription Drugs From International Mail Order Pharmacies." *See* 2013 P.L. Ch. 373, *available at* http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0060&item=4&snum=126 (last visited Sept. 10, 2013). The Governor declined to take action on the bill, so the Importation Law became law without the Government's signature on June 27. *See id.* The effective date of the Importation Law is 90 days after the conclusion of the legislative session on July 10—that is, October 9, 2013.

47. The Importation Law amends the Maine Pharmacy Act and exempts from the Act's licensing requirements any "licensed retail pharmacy that is located in Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia or New Zealand that meets its country's statutory or regulatory requirements." *Id.* It further provides that any such foreign mail-order pharmacy "may export prescription drugs by mail or carrier to a resident of this State for that resident's personal use." *Id.*

48. The Importation Law further exempts from the Maine Pharmacy Act's licensing requirements any "entity that contracts to provide or facilitate the exportation of prescription drugs from" a foreign mail-order pharmacy, and provides that any such entity "may provide or facilitate the provision of prescription drugs from that pharmacy by mail or carrier to a resident

of this State for that resident's personal use." *Id.*

49. In addition, the Importation Law provides that nothing in Maine law "may be construed to prohibit" a resident of the State "from ordering or receiving prescription drugs for that individual's personal use from" an authorized foreign pharmacy. *Id.* It also provides that Maine law will no longer prohibit foreign pharmacies "from dispensing, providing, or facilitating the provision of prescription drugs from outside the United States by mail or carrier to a resident of this State for personal use." *Id.*

50. The Importation Law does not condition the importation of prescription drugs on compliance with federal law, including federal law concerning the approval, manufacture, labeling, transportation, and maintenance of pharmaceuticals. Nor does it condition the importation of drugs on a certification of safety and cost-effectiveness and a waiver from the Secretary of Health and Human Services, as required by the MMA. *See* 21 U.S.C. § 384(l).

51. The Importation Law thus authorizes and facilitates federally-prohibited importation of prescription drugs, including importation performed by or with the assistance of state-run insurance programs, private health insurance providers, and individuals.

F. The Importation Law Is Directly Contrary To Federal Law And Harmful

52. Although the Importation Law is the first of its kind, the notion of importing pharmaceuticals from foreign countries is not a new one. Indeed, Maine acted against a backdrop of the FDA's clear warnings of the serious risks posed by imported prescription drugs.

53. By enacting the Importation Law, Maine has also knowingly acted directly contrary to federal law. The FDA has repeatedly stated that federal law preempts any and all state laws that would facilitate the private importation of foreign pharmaceutical products. *See, e.g.*, Guinn Letter ("Any state law that legalizes imports in contravention of the FFDCA would be preempted by federal law."); *see generally* Importing Prescription Drugs, Letters To State

And Local Officials, *available at* http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm (last visited Sept. 10, 2013) (collecting the agency's "official communication[s]" to officials in Hawaii, Minnesota, Washington, Maryland, Oregon, Texas, Nevada, Rhode Island, District of Columbia, Massachusetts, Wisconsin, New Hampshire, North Carolina, Illinois, and California).

54. Indeed, based on the serious legal and public-health concerns outlined above, the FDA has advised officials in at least 15 states that state laws purporting to authorize the importation of prescription drugs from Canada or other foreign countries—including state laws limiting such importation to private individuals for their personal use—run afoul of the FDCA and are preempted. *See, e.g.*, Importing Prescription Drugs, Letters To State And Local Officials, *available at* http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm (last visited Sept. 10, 2013) (collecting letters to officials in Hawaii, Minnesota, Washington, Maryland, Oregon, Texas, Nevada, Rhode Island, District of Columbia, Massachusetts, Wisconsin, New Hampshire, North Carolina, Illinois, and California).

55. As the FDA has reasoned: "Clearly, Congress created [the] import provisions in the FDCA with the goal of controlling the types of drugs that could be legally imported into the United States." Guinn Letter. This federal scheme "is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated." *Id.* Thus, "[b]y definition, the scheme cannot allow the individual states to enact laws that erode federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports." *Id.* "Licensure of Canadian" or other foreign "pharmacies by [a] State . . . would be inconsistent with the plain objectives of the FDCA if such licensure authorized those . . . pharmacies to ship into the United States drugs that violate the provisions of the FDCA." *Id.*

56. The FDCA also includes a special restriction on importation of "American goods returned," directing that, except in certain limited circumstances, no prescription drug "which is manufactured and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." *See* 21 U.S.C. § 381(d)(1).

57. The goal of this restriction is to protect patients from counterfeit and adulterated prescription drugs. In particular, Congress found that "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." Prescription Drug Marketing Act, Pub. L. 100–293 § 2 (Apr. 22, 1988).

58. The Importation Law conflicts with the "American goods returned" provision and its underlying safety rationale because it authorizes foreign mail-order pharmacies to import drugs into Maine—whether or not those drugs were originally produced in the United States—even though Congress has found such imports to pose unacceptable health and safety risks to the American public.

G. The Importation Law Exposes Maine Patients To A Risk Of Serious Harm

59. The Importation Law thus will harm Maine patients by exposing them to the health and safety risks that federal law and the Maine Pharmacy Act were enacted to minimize.

60. In the first place, as explained, drugs obtained from a foreign source may not have been approved by the FDA or otherwise satisfy the federal-law standards for distribution within or importation to the United States. Thus, as the FDA has recognized, such drugs may be misbranded, adulterated, counterfeit, or not properly handled and transported as required by federal law. Such substandard drugs may pose significant health risks to Maine patients who use them, including the risks of serious permanent injury or even death.

61. Moreover, foreign mail-order pharmacies are not subject to the verification, DUR, recordkeeping, counseling, or privacy requirements of OBRA, Maine law, and HIPAA. Foreign mail-order pharmacies therefore are not required by federal or state law to verify the identity of the prescribing practitioner, to maintain records regarding the patient's health and drug history, to examine the patient's record for potentially life-threatening drug-disease contraindications or drug-drug interactions, or to advise patients regarding the proper handling and use of prescription drugs. Accordingly, even foreign mail-order pharmacies that dispense genuine prescription drugs may not give Maine patients proper instructions regarding their use. In addition, such pharmacies may not properly warn Maine patients regarding, or prevent, drug-disease contraindications or drug-drug interactions. Maine patients thus will be exposed to the risk of serious disease or even death from the improper use of prescription drugs or avoidable drug-disease contraindications or drug-drug interactions.

62. Maine patients who receive prescription drugs from both a foreign mail-order pharmacy and a Maine pharmacist face the risk that the Maine pharmacist will have incomplete or inaccurate information regarding the patient's medical or drug histories. For example, patients may not know or may not communicate to the Maine pharmacist accurate information regarding the prescription drugs they obtained from the foreign source, such as the description, dosage, or the patient's use history. The Maine pharmacist will have no record of that information because it was not the pharmacist that filled the prescription. Moreover, even if the patient believes she has perfect information regarding the foreign drugs, those drugs may be misbranded, adulterated, counterfeit, mislabeled, or expired. Thus, it may be impossible for the Maine pharmacist to detect and to prevent dangerous drug-disease contraindications or drug-drug interactions, to advise the patient on potential side or adverse effects, or to provide proper

instructions regarding drug use.

63. Thus, by undermining and circumventing the exclusive license of Maine pharmacists to dispense prescription drugs, the Importation Law creates informational deficits and undermines the ability of licensed Maine pharmacists and pharmacies to discharge their legal, ethical, and fiduciary duties to protect their patients from potentially deadly misuse of prescription drugs.

64. The sponsors of the Importation Law justified it on a cost-savings rationale, arguing that the Law will reduce prices to consumers because foreign prescription drugs can be less expensive than their domestic counterparts. Thus, even the sponsors contemplate that the Importation Law will cause a transfer of market share away from safe, regulated domestic pharmacies and to unsafe, unreliable, and unregulated foreign mail-order pharmacies.

65. At the same time, the Importation Law permits foreign mail-order pharmacies to import prescription drugs into the United States even though those pharmacies are not subject to the requirements of federal or Maine law, are not subject to the oversight of the Food and Drug Administration, and are subject to different and less stringent safety requirements imposed by foreign governments. The foreign mail-order pharmacies therefore cannot perform the function of protecting patient safety and promoting consumer confidence in prescription drugs that domestic pharmacies perform under federal law.

66. Domestic pharmaceutical manufacturers invest substantial money, time, and resources in producing high-quality prescription drugs that comport with the strict requirements of federal law, and in guaranteeing that only the safest products are ever delivered to pharmacies and patients. In the event that a mislabeled, adulterated, counterfeit, or expired prescription drug reaches a patient in the United States, the patient inevitably will blame the manufacturer of the

genuine product that the patient expected to receive. Thus, the manufacturer of the genuine product will suffer a reputational loss, loss of goodwill, and loss of consumer confidence, regardless of whether the manufacturer is to blame or could have done anything to block that import.

67. The organizational plaintiffs also are expending considerable resources and time to educate the public about the health and safety risks posed by the unregulated importation of foreign drugs and importation of American-made drugs, and will continue to expend considerable resources and time on such education. The organizational plaintiffs also have expended considerable resources and time on public advocacy efforts related to the Importation Law and in educating their members on the Importation Law and all applicable federal and state laws. The Importation Law thus creates a drain on the organizational plaintiffs' time and resources, which those plaintiffs would otherwise devote to serving the public as well as its members in other ways.

COUNT I

(Violation of the Supremacy Clause)

68. Plaintiffs reallege and incorporate by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

69. The Supremacy Clause of the U.S. Constitution provides that federal law "shall be the supreme law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI.

70. Federal law has created an exacting statutory and regulatory scheme that regulates the manufacturing processes, labeling, and packaging of pharmaceutical products. 21 U.S.C. §§ 355; *see also* 21 C.F.R. §§ 201.15(c), 314.50. These federal requirements protect the American people from dangerous or ineffective pharmaceutical products.

71. Federal law specifically prohibits importation or introduction into interstate commerce of any prescription drugs that have not been labeled in accordance with federal law, including requirements pertaining to the content of warning labels and use of the English language. *See* 21 U.S.C. §§ 352, 353; 21 C.F.R. § 201.15(c). Federal law also prohibits importation or introduction into interstate commerce of any prescription drug dispensed without a valid prescription issued by a licensed practitioner. *See* 21 U.S.C. § 353(b); *id.* §§ 331(a)-(d).

72. As the Food and Drug Administration (FDA) has repeatedly stated, foreign pharmaceutical products virtually never satisfy the requirements of federal law, including safety requirements pertaining to manufacture, labeling, and transportation.

73. The FDA has advised over a dozen states that state laws purporting to license or otherwise authorize the importation of foreign pharmaceuticals would violate federal law and be preempted pursuant to the Supremacy Clause of the U.S. Constitution.

74. The Importation Law encroaches on a field whose governance belongs exclusively to the federal government, and therefore is preempted under the Supremacy Clause. Moreover, the Importation Law stands in conflict with the considered policy of the federal government concerning the importation of foreign prescription drugs, and so is preempted under the Supremacy Clause. Finally, the Importation Law is an obstacle to the achievement of federal objectives and, for this reason too, is preempted under the Supremacy Clause.

75. The Supremacy Clause preempts the Importation Law and supplies Plaintiffs with a direct entitlement to relief.

COUNT II

(Violation of the Foreign Commerce Clause)

76. Plaintiffs reallege and incorporate by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

77. The Constitution grants Congress the power to "regulate Commerce with foreign Nations." U.S. CONST. art. I, § 8 cl. 3. The federal power over foreign commerce is plenary, to the exclusion of the states or any state regulation.

78. The Importation Law intrudes on a domain of exclusive federal jurisdiction—namely, the importation of foreign substances, including pharmaceuticals.

79. The Importation Law prevents the United States from speaking with one voice in the area of international pharmaceutical trade.

80. The Foreign Commerce Clause preempts the Importation Law and directly supplies Plaintiffs an entitlement to relief.

COUNT III

(28 U.S.C. § 1983)

81. Plaintiffs reallege and incorporate by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

82. 42 U.S.C. § 1983 provides a civil cause of action to any person who is deprived of rights guaranteed by the U.S. Constitution or federal laws by another under color of State law.

83. Plaintiffs are entitled to declaratory and injunctive relief against Maine and its agents pursuant to § 1983.

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for the following relief:

1. A declaration under 28 U.S.C. § 2201, an order, and a judgment that the Importation Law violates the Supremacy Clause and Foreign Commerce Clause of the U.S. Constitution;

2. An injunction prohibiting Maine, its officials, and Defendants from acting pursuant to the Importation Law, taking any steps to implement the Importation Law, or otherwise facilitating the importation of pharmaceuticals;

3. All costs and attorneys' fees pursuant to any applicable statute or authority;

4. Any other relief that this Court deems just and proper.

Dated: September 10, 2013

/s/ Michael A. Carvin
Michael A. Carvin (*pro hac vice* pending)

/s/ John M. Gore
John M. Gore (*pro hac vice* pending)

/s/ Richard M. Re
Richard M. Re (*pro hac vice* pending)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Fax: (202) 626-1700

/s/ David B. McConnell
David B. McConnell

/s/ Joseph G. Talbot
Joseph G. Talbot
PERKINS THOMPSON
One Canal Plaza, 9th Floor
Portland, Maine 04101
Telephone: (207) 774-2635
Facsimile: (207) 871-8026

ATTORNEYS FOR PLAINTIFFS